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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,793	09/19/2003	Edward J. Kaplan	KAP 100 CIP	6738

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,793	KAPLAN, EDWARD J.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE Acknowledged

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Status of Application

2. Acknowledgement is made of amendment filed on 10/31/2007. Upon entering the amendment, the claims 1-35 are cancelled and new claims 36-55 are acknowledged. The pending claims 36-55 are presented for examination.

Response to Arguments

3. Applicant's arguments filed on 10/31/2007 with respect to claims 1-35 under U.S.C. 103(a) have been fully considered but they are moot in view of new ground(s) of rejection due to the scope changes made into the newly amended claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is rendered vague and indefinite by the use of the phrase" wherein the spacers are made of a color, texture, diameter, hardness, or shapes for identification and demarcation". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. It is unclear whether it refers to spacers are made of same or different color, texture... within the composition. An ordinary skilled artisan would not be apprised of the metes and bound s of the term and would not be able to ascertain its meaning based on applicant's disclosure.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora et al. (US 2001/0044567 A1) and Grimm (US 6,010,446) in view of Coniglione (US 5,713,828).

Zamora discloses a branchytherapy device comprising a biocompatible biodegradable component (i.e. polymeric material), a non-radioactively therapeutic component and a biodegradable radiopaque marker (see abstract). The biodegradable component includes polymers (e.g. Poly (D,L-lactide) poly (L-lactide, (polyglycolide, poly (L-lactide-co-glycolide) that are same as those claimed (see page 2, para 0025 and page 5, para 0055). And also the biocompatible polymer such as poly (hydroxybutyrate) is included that can read as biocompatible elastic carrier to form an elastic brachytheraphy seed (see page 4, para 0049) since they are essential same compounds. The size and shape of the seeds are within the scope of those claimed (see page 5, para 0057+). And also the outer surface of device have sufficient permanence or persistence so that the radioactive source material remains localized at the site of implantation at all times for use in treatment of diseases, including radiation therapy of cancers (see 0029 and 0031). The non-radioactive therapeutic component includes chemotherapeutic agent such as cisplatin bleomycin, a radiosensitizer drug such as 5-halo uracil compounds (see page 7, para 0080). Zamora also teaches the radiopaque marker which includes various markers that are biodegradable such as platinum, tantalum and bismuth (see page 4, para 0051), where these markers are

same as one required by claims, thus non-radionuclide imaging marker requirement is inherently met. The seeds of the device may be implanted singly, or may utilize suture strands, webs, meshes or other means to group the devices in a desired manner (see page 7, para 0085+). Methods of making the seeds are disclosed on pages 5-8, which include the steps as claimed.

Grimm discloses a spacer element for use between radioactive seeds in needle implant treatment for prostate cancer, comprising: a spacer element having a center section and two end sections, the two end sections being configured, respectively, to hold an adjacent radioactive seed, such that a spaced plurality of radioactive seeds results from the connection of successive spacers and seeds; wherein the spacer element is made from a material which is absorbable in living tissue; and wherein a combination of spacer element and radioactive seeds can be fitted within a needle for subsequent insertion into the prostate treatment thereof (see col. 1 lines 65+).

Zamora and Grimmer fails to disclose one or more biodegradable structures effective to prevent migration and one more compliant setal structures which impart adhesive properties upon implantation of the seed into a target tissue.

Coniglione discloses a radioactive seed for interstitial implantation branchytherapy device formed from a hollow-tube-shaped seed-substrate, allowing the easy association of the device with suture material. And also discloses that shaped device minimizes the chance of migration of implanted seeds due to better attachment to tissue (see abstract). And also the entire device is provided with a biologically compatible, radiation-permeable, surface-sealing layer having perforations through the

walls of the tube, and the perforations may be oriented in any direction. And also discloses the hallow-tube design of the device permits the growth of tissue into the device to anchor the device at the application site and minimize the potential for migration (see col5. lines 48-54). And further discloses the branchytherapy device has special application to the form of branchytherapy wherein seeds are associated with flexible suture material and are thereby held in a compliant array in the neoplastic tissue by the suture while their radiation dose is delivered (see col.5 lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate branchytherapy seeds having one or more biodegradable structures effective to prevent migration and one more compliant setal structure which impart adhesive properties upon implantation of the seed into a target tissue disclosed by Zamora and Grimmer. In view of Coniglione, motivation would come from the branchytherapy device disclosed specifically intended to ease the task of surgeons, urologists, radiation therapists, radiologists, and others who use branchytherapy, e.g. the interstitial implantation of radioactive sources into tumorous tissue for the purpose of irradiating and thus killing malignant cells.

When these references are taken together, one would have been motivated to extend Coniglione's teaching to add branchytherapy seeds having one or more biodegradable structures effective to prevent migration and one more compliant setal structure which impart adhesive properties upon implantation of the seed into a target tissue to maximize therapeutic efficacy. As suggested by cited references, one would have reasonably expected successful addition of Coniglione branchytherapy seeds

(such as a hollow-tube shaped substrate that have perforations through the walls of the tube) because the effectiveness, extra benefits (i.e., minimize the potential migration of seeds, and flexibility of the device allows a surgeon to effectively react to challenges not revealed by the presurgical workup of the patient) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). Claims 36-40, 45, 47-55 are rejected on the ground of nonstatutoryobviousness type double patenting as being unpatentable over claims 1-3, 5,10,12,13, 30, 32, 35, 38 and 41 of US 6,746,661 B2. Although the conflicting claim is not identical, they are patentably distinct from each other because claim of the instant application is drawn to a brachytherapy seed for implantation into a subject comprising, a biocompatible carrier, one or more therapeutic components, an imaging, radiopaque or other diagnostic marker, and one or more structures to prevent migration, wherein the seed is elastic and has size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10gauge), while the US pat. Application is a branchy therapy seed for implantation into a subject comprising one or more micropsheres, wherein each microsphere comprises at least

one component selected from the group consisting of biocompatible component, a therapeutically active component and a radiopaque marker; and brachytherapy seed has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge). Both require brachytherapy seeds, biocompatible component, radiopaque marker and therapeutic agent. Thus, the instant claim is within the scope of the claim of the US pat. 6,746,661. Thus scope is overlapping each other and properly included in the rejection because hey are patentably distinct from each other. Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

Zohreh Fay
Primary Examiner
Art Unit 1618